PUBLIC VERSION

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

Before The Commission

In the Matter of **CERTAIN RUBBER ANTIDEGRADANTS, COMPONENTS THEREOF, AND PRODUCTS CONTAINING SAME**	**Investigation No. 337-TA-533**

PETITION OF THE OFFICE OF UNFAIR IMPORT INVESTIGATIONS FOR REVIEW OF FINAL INITIAL DETERMINATION AND RECOMMENDED DETERMINATION

Lynn I. Levine, Director
Jeffrey R. Whieldon, Supervisory Attorney
Juan Cockburn, Investigative Attorney

OFFICE OF UNFAIR IMPORT INVESTIGATIONS
U.S. International Trade Commission
500 E Street, S.W., Suite 401-Q
Washington, D.C. 20436
(202) 205-2572
(202) 205-2158 (Facsimile)

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I. INTRODUCTION

On February 17, 2005, the Administrative Law Judge issued his initial determination ("ID"), wherein he found a violation of Section 337 by Respondents Sinorgchem Co., Shandong ("Sinorgchem") and Sovereign Chemical Company ("Sovereign"),and found no violation Respondent Korea Kumho Petrochemical Co., Ltd. ("KKPC"). ID at 138. The ID's finding of violation is based on its determination that Sinorgchem's accused process infringes claims 30 and 61 of U.S. Patent 5,117,063 ("the '063 patent") and claims 7 and 11 of U.S. Patent 5,608,111 ("the '111 patent").[1] ID at 97, 138. The ID also determined that Flexsys had demonstrated that a domestic industry exists with respect to the patents at issue.[2] ID at 122. The ID further

[1] Sovereign's alleged violation is premised on the fact that it imports into and sells in the United States 6PPD made by Sinorgchem. ID at 102.

[2] The domestic activities of Flexsys had previously been determined to satisfy the economic criterion of Section 337. Order No. 28, October 13, 2005.

determined that Respondents had not demonstrated that any of the claims were invalid as obvious under § 103 or indefinite under § 112, ¶ 2. ID at 113, 118-19. Finally, the ID recommended that if the Commission find a violation, a limited exclusion order should issue against 4-ADPA and 6PPD made by Sinorgchem and imported by Sovereign, and that a bond should not be imposed during the Presidential review period. ID at 131, 134.

The Office of Unfair Import Investigations ("OUII") seeks review of (1) the ID's construction of the term "controlled amount of protic material;" (2) its determination of infringement based on such construction; and (3) its determination that such construction satisfies the definiteness requirements of section 112, ¶ 2.[3]

As demonstrated below, the ID's construction of the limitation "controlled amount of protic material" is legally erroneous. Specifically, with respect to this construction, the ID erred by (1) ignoring the express definition of the term at issue found in the specifications of both patents; (2) relying upon extrinsic expert testimony that is contrary to the intrinsic evidence and thereby disregarding the patentees' express definition of the maximum allowable volume of water when water is the protic material and aniline or dimethylsulfoxide ("DMSO") is the solvent;[4] (3) requiring a showing that the patentees intended to define the limitation in the

[3] Certain of the ID's factual findings relating to the Wohl references regarding the first two elements of the claims at issue are clearly erroneous. Moreover, these findings result from a construction that appears to differ from that used with respect to the ID's determination of infringement.

[4] The inventors defined the maximum amount of water when aniline and DMSO are the solvents (and water is the "protic material") as "up to about 4%" and "about 8%," respectively. [ ] aniline is the relevant solvent

(continued...)

specification; and (4) relying upon a later-issued patent to broaden the scope of a term common to both the parent and CIP patents in direct contravention of precedent, including the case relied on in the ID for support.

The ID's erroneous construction of the limitation, in turn, results in the erroneous determination that Respondent Sinorgchem's accused process infringes the asserted claims and that Flexsys' process satisfies the technical requirements of Section 337. Finally, the erroneous construction also results in an incorrect conclusion that the asserted claims are definite.

II. SUMMARY OF THE INITIAL DETERMINATION

A. The ID's Construction

The parties disputed the term "controlled amount of protic material" that is present in each of the asserted claims. The ID adopted Flexsys' proposed construction, and determined that the term should be construed as follows:

> The term a "controlled amount" of protic material means that the amount of protic material (which is not limited to water) should be controlled between (1) an upper limit of protic material which is the amount of protic material beyond which the reaction between nitrobenzene and aniline (or substituted aniline) is inhibited and (2) a lower limit of protic material which is the amount of protic material below which the desired selectivity for 4-ADPA intermediates is not maintained.

ID at 78-79.

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[4] (...continued)
herein for purposes of both claim construction and the infringement analysis.

In reaching this determination, the ID summarizes the non-asserted claims of each of the patents at issue, along with their specifications and examples.[5] The ID also relies on a portion of the prosecution of the '111 patent, where the inventors corrected their erroneous calculation of water content that was set forth in Table 7 of Example 9 of the '063 patent and set forth the method they used to "properly calculate" the percentage of water in Example 9.[6] ID at 49-78. The ID concludes that the claimed "protic material" encompass a variety of compounds, including water and that the claimed "suitable solvents" encompass a variety of solvents, including aniline. ID at 79-80.

The ID, at 59-60 sets forth the following text from the specifications of both patents (CX1, Col. 4, ln. 31 through Col 5, ln. 4; CX3, Col. 5, lns. 27-65), which is thereafter referred to by the Judge in his ID as "the PARAGRAPH." For consistency, OUII will use the term "the PARAGRAPH" when referring to the following section:

> Control of the amount of protic material present in the reaction is important. Generally, when the reaction is conducted in aniline, water present in the reaction in an amount greater than about 4% H2O, (based on volume of the reaction mixture) inhibits the reaction of the aniline with the nitrobenzene to an extent where the reaction is no longer significant. Reducing the amount of water to

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[5] The '111 patent is a continuation-in-part of the application that issued as the '063 patent. Hence, the specification of the '111 patent is essentially identical to that of the '063 patent. The major difference between the two specifications is that the specification of the '111 patent contains material specific to the "inventions" claimed therein, including additional examples numbered 13 through 21.

[6] The inventors' original calculations of the water content in Table 7 was erroneous. Despite having available the inventors' explanation of their method of calculation offered during prosecution of the '111 patent of their method, the original calculations of the water content in Example 10 of both patents by Flexsys' expert Dr. Crich were also erroneous. *See* Crich, Tr. 995-97.

> below the 4% level causes the reaction to proceed in an acceptable manner. When tetramethylammonium hydroxide is utilized as a base with aniline as the solvent, as the amount of water is reduced further, *e.g.*, down to about 0.5% based on the volume of the reaction mixture, the total amount of 4-nitrodiphenylamine and 4-nitrosodiphenylamine increases with some loss in selectivity so that more 2-nitrodiphenylamine is produced but still in minor amounts. Thus, the present reaction could be conducted under anhydrous conditions. A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H2O based on the volume of the reaction mixture when aniline is utilized as the solvent. The upper limit for the amount of protic material present in the reaction varies with the solvent. For example, when DMSO is utilized as the solvent and tetramethylammonium hydroxide ["TMAH"] is utilized as the base, the upper limit on the amount of protic material present in the reaction is about 8% H2O based on the volume of the reaction mixture. When aniline is utilized as a solvent with the same base [TMAH], the upper limit is 4% H2O based on the volume of the reaction mixture. In addition, the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems. However, it is within the skill of one in the art, utilizing the teachings of the present invention, to determine the specific upper limit of the amount of protic material for a specific solvent, type and amount of base, base cation and the like. The minimum amount of protic material necessary to maintain selectivity of the desired products will also depend on the solvent, type and amount of base, base cation and the like, that is utilized and can also be determined by one skilled in the art.

CX1, Col. 4, ln. 31 through Col 5, ln. 4; CX3, Col. 5, lns. 27-65 (emphasis added (italics, OUII, bolded, ID) Denonimated "the PARAGRAPH" in the ID. *See* ID at 59-60.

The ID concludes that the general language of the last three sentences at the end of "the PARAGRAPH" (commencing with the words "In addition, the amount of . . .") supports its construction of the limitation. ID at 82. The ID, however, does not address the specific language in "the PARAGRAPH" (CX1, col. 4, lns. 48-60; CX3, col. 5, lns. 48-55) that defines the term "controlled amount of protic material" or OUII's and Respondents' contentions relating to this section.

The ID addresses Respondents' secondary arguments that were premised on,[7] *inter alia*, *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir.2001) and *Alloc, Inc. v. International Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003). ID at 88-89. Contrary to the cases cited by Respondents, "the administrative law judge finds that the patentees *did not intentionally* define controlled amount of protic material' to exclude Example . . . . . .[8] Moreover, when aniline is the solvent, claim 29 of the '111 patent specifically recites . . . 'up to 13.8 volume %,' which means that 'controlled amount of protic material' cannot be defined as to have an upper limit of 4% when aniline is the solvent."[9] ID at 89 (emphasis added).

As shown below, the ID erred as a matter of law by relying upon extrinsic expert testimony to disregard the patentees' express definition of the term "controlled amount of protic material." ID at 90). The ID also erred as a matter of law by relying upon a later-filed

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[7] OUII's and Respondents' primary argument below was that the patentees acted as their own lexicographers by virtue of the language set forth in "the Paragraph," particularly the use of quotation marks around the phrase "controlled amount," *e.g.* "A 'controlled amount' of protic material is an amount . . . ." *See*, *e.g.*, Commission Investigative Staff Post-Hearing Brief at 12-17; Respondents' Post-Hearing Brief at 22-27.

[8] A patentee's "intention" is irrelevant when determining whether the patentee has acted as his/her own lexicographer. *See*, *e.g.*, *Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004).

[9] The law is clear that one cannot broaden the enforceable scope of a patent by virtue of a CIP that contains claims with broader limitations. *See*, *e.g.*, *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003). Thus, the ID's reliance upon the express terms of a claim of the '111 patent to broaden the enforceable scope of all claims in both patents is contrary to the holding in *Omega*, *supra*.

application to construe terms in an earlier application in order to broaden the scope of the term at issue that is present in both patents.

B. Non-Infringement

The ID determined that Sinorgchem's process literally infringes the asserted claims based upon its construction of the limitation "controlled amount of protic material," which was the only disputed element in dispute. ID at 101-02.[10]

The ID's infringement determination is premised upon its use of a legally erroneous claim construction. Therefore, the infringement determination constitues legal error.

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[10] In OUII's view, the ID's construction would lead to a finding of infringement of the asserted claims by almost any process wherein aniline and nitrobenzene are brought together in the presence of a base, and measurable amounts of 4-ADPA intermediates are produced.

The ID determined that the Wohl experiments do not satisfy elements (a) or (b) of claim 30 of the '063 patent or claim 7 of the '111 patent. The ID found that Wohl evaporated all of the water from the reaction, and that Wohl "did not maintain a minimum necessary to maintain the selectivity of the desired 4-ADPA intermediates." Based on the foregoing, the ID concluded that Wohl does not teach the presence of a "solvent system" throughout the reaction or a "controlled amount of protic material." ID at 111-12.

In contrast, in distinguishing Wohl before the USPTO, the patentees did not raise either point. They described Wohl as a reaction between aniline with nitrobenzene and a base under anhydrous conditions. The inventors distinguished Wohl on the ground that Wohl discloses anhydrous conditions. *See* ID at 75-77. In this regard, OUII notes that the patents at issue teach that the inventions may be practiced under anhydrous conditions. CX1, col. 4, lns. 46-48; CX3, col. 5, lns. 41-43.

Further, both the European patent office ("EPO") and the Korean courts determined that the Wohl experiments satisfy these two elements and issued final rejections of the European and Korean counterparts of claim 1 of the '063 patent, which claim only requires the production of 4-ADPA intermediates, *i.e.*, the first two elements of each of the asserted claims. *See*, *e.g.*, EPC: Rains, Tr. 773; RX49 at 2; RX835 at 3, ¶2.2, at 5, ¶2.5, at 6, ¶2.6; RX43 at FA030508; RX848 at KKPC-ITC 09164T, KKPC-ITC 09168T, and KKPC-ITC 09168T.

C. Indefiniteness

The ID determined that the limitation a "controlled amount of protic material," when construed as follows, is definite:

> the amount of protic material (which is not limited to water) should be controlled between (1) an upper limit of protic material which is the amount of protic material beyond which the reaction between nitrobenzene and aniline (or substituted aniline) is inhibited and (2) a lower limit of protic material which is the amount of protic material below which the desired selectivity for 4-ADPA intermediates is not maintained.

ID at 119. The ID's determination in this regard is based upon its factual finding that the examples in the specifications of both patents and the prosecution history of the '111 patent provide sufficient information that would enable one of ordinary skill in the art to determine the specific upper and lower limits of protic material for a specific set of reaction conditions. ID at 116, 117, 119.

The ID relies upon clearly erroneous findings of fact and a misapplication of applicable precedence in support of its determination that the limitation at issue is definite.

III. STANDARD OF REVIEW

Pursuant to Commission Rule 210.43(b)(1), a party seeking review must specify one or more of the following grounds upon which review of the initial determination is sought:

(i) that a finding or conclusion of material fact is clearly erroneous;

(ii) that a legal conclusion is erroneous, without governing precedent, rule or law, or constitutes an abuse of discretion; or

(iii) that the determination is one affecting Commission policy.

Commission Rule 210.43(d)(2) provides that the Commission will grant a petition and order review "if it appears that an error or abuse of the type described in paragraph (b)(1) of this section is present or if the petition raises a policy matter connected with the initial determination, which the Commission thinks it necessary or appropriate to address." 19 C.F.R. § 210.43(d)(2).

The ID contains three erroneous determinations of which OUII seeks review:

(1) the ID's construction of the term "controlled amount of protic material;"

(2) the ID's determination that Sinorgchem's process infringes the claims at issue;[11] and

(3) the ID's determination that the asserted claims as construed therein are "definite."

As summarized in Section II above, the ID committed numerous legal errors in arriving at its construction of the "controlled amount of protic material" limitation, *e.g.*, ignoring the patentees' express definition, relying upon extrinsic expert testimony that is contradicted by intrinsic evidence, and using a later-issued patent to construe the same term in a prior- issued patent.

IV. LEGAL STANDARD OF CLAIM CONSTRUCTION

Claims must be interpreted and given the same meaning for the purpose of analyzing both validity and infringement issues in a case. *White v. Dunbar*, 119 U.S. 47, 51 (1886); *Southwall*

[11] Neither Sinorgchem's nor Flexsys' processes are covered by *any* claim of the '063 or '111 patents under the proper construction of the "controlled amount of protic material" limitation [ ] Hence, review of the ID's infringement determination implicates its determination that Flexsys' process satisfies the technical requirements of Section 337.

Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1578 (Fed. Cir. 1995). Claim interpretation is a matter of law exclusively for the court and, on appeal, is subject to *de novo* review. *Cybor Corp. v. FAS Technologies Ltd.*, 138 F.3d 1448, 1455-56 (Fed. Cir. 1998) (*en banc*); *Markman v. Westview Instruments, Inc.*, 52 F.3d 969, 976 (Fed. Cir. 1995) (en banc), aff'd, 116 S.Ct. 1384, 38 USPQ2d 1461 (1996) ("*Markman*").

In interpreting a claim, three sources must be considered: the claims, the specification, and the prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ('*Phillips*"); *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576,1582 (Fed. Cir. 1996) ("*Vitronics*"); *Markman*, 52 F.3d at 976. The *Phillips* court stated:

> It is a "bedrock principle" of patent law that "the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova [/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*], 381 F.3d [1111] at 1115 [Fed Cir. 2004); *see also Vitronics*, 90 F.3d at 1582 ("we look to the words of the claims themselves ... to define the scope of the patented invention"); *Markman*, 52 F.3d at 980 ("The written description part of the specification itself does not delimit the right to exclude. That is the function and purpose of claims.").

Phillips, 415 F.3d at 1312. The specification may act as a sort of dictionary, explaining the invention and *defining terms used in the claims*. *Phillips*, 415 F.3d at 1313; *Vitronics*, 90 F.3d at 1582-83; *Markman*, 52 F.3d at 979.

The specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In the instance where the inventor has dictated the correct claim scope, the inventor's intention, as expressed in the specification, *is regarded as dispositive*. *Phillips*, 415 F.3d at 1316; *Astrazeneca AB v. Mutual Pharmaceutical Co.*, 384 F.3d 1333, 1339-40 (Fed. Cir. 2004) ("*Astrazeneca*"*); Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381

F.3d 1111, 1117 (Fed. Cir. 2004) ("*Innova*") ("Because the inquiry into the meaning of claim terms is an objective one, a patentee who notifies the public that claim terms are to be limited beyond their ordinary meaning to one of skill in the art will be bound by that notification, even where it may have been unintended."); *Abbott Laboratories v. Novopharm Ltd.*, 323 F.3d 1324, 1330 (Fed. Cir. 2003) ("*Abbott Labs*") (Term defined in specification governs, hence "the district court did not err by reading the patentee's definition from the specification into the claim."); *Alloc, Inc. v. International Trade Comm'n*, 342 F.3d 1361, 1370 (Fed. Cir. 2003) ("*Alloc*") (claim limited where specification makes clear that the claimed invention is narrower than the claim language might imply, citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1345 (Fed. Cir.2001)); *Durel Corp. v. Osram Sylvania Inc.*, 256 F3d 1298, 1303-04 (Fed. Cir. 2001) ("*Durel*") (Claim term defined in specification governs). Contextual statements in the specification can be used to show a disavowal of the scope of disputed claim terms. *See Astrazeneca*, 384 F.3d at 1337 (quoting *Texas Digital Systems, Inc. v. Telegenix*. 308 F.3d 1193, 1204 (Fed. Cir. 2002)); Alloc, 342 F.3d at 1370. However, it is the claims, and not the written description part of the specification, that delimit the right to exclude. *Phillips*, 415 F.3d at 1312; *Markman*, 52 F.3d at 979.

Moreover, the same term or phrase should be interpreted consistently where it appears in claims of common ancestry, with interpretation of the earlier claim governing the interpretation of the latter claim. *See*, *e.g.*, *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1333-34 (Fed. Cir. 2003) ("*Omega*") (scope of term in parent application limits scope of same term in a *later* patent that issued on a CIP application). Similarly, arguments made during a prosecution with

respect to claim elements that are common to patents of common ancestry are part of the prosecution history of those patents. *See*, *e.g.*, *Alloc*, 342 F.3d at 1371-72; *Biovail Corp. Int'l v. Andrx Pharmaceuticals Inc.*, 239 F.3d 1297, 1301 (Fed. Cir. 2001) ("*Biovail*") ("When multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any patent that has issued applies with equal force to *subsequently issued patents that contain the same claim limitation*," quoting *Elkay Mfg. v. Ebco Mfg.*, 192 F.3d 973, 980 (Fed. Cir. 1999) ("*Elkay*") (emphasis added). Accordingly, the applicant can be bound by statements made during the prosecution of a parent or sibling application that would preclude a contradictory claim construction based on the later-filed patent.

Extrinsic evidence may also be considered, if needed, to assist in determining the meaning or scope of technical terms in the claims. *Phillips*, 415 F.3d at 1318; *Vitronics*, 90 F.3d at 1582-83. Extrinsic evidence is not needed to construe a claim if the court can resolve the ordinary meaning of the claim terms solely by considering the intrinsic evidence. *Id*. Moreover, in *Phillips*, the Federal Circuit recently limited the weight to be accorded to extrinsic evidence. *See generally Phillips*, 415 F.3d at 1317-23. The Court in *Phillips* emphasized the importance of the claims, specification, and file history, in that order, in construing claim terms. *Id.* at 1313-17. The *Phillips* decision appears to give less significance to the file history in construing claims by stating that because "the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification *and thus is less useful for claim construction purposes*." *Id.*, 415 F.3d at 1317. (emphasis added).

V. CONSTRUCTION OF THE CLAIMS AT ISSUE

The ID determined that Sinorgchem's accused method infringes asserted claims 30 and 61 of the '063 patent ("CX1"), and claims 7 and 11 of the '111 patent ("CX3"). The '111 patent issued on a continuation-in-part application from the parent application that issued as the '063 patent. CX3. The ID adopted Complainant Flexsys' proposed construction of the term "controlled amount of protic material" as follows:

> The term a "controlled amount" of protic material means that the amount of protic material (which is not limited to water) should be controlled between (1) an upper limit of protic material which is the amount of protic material beyond which the reaction between nitrobenzene and aniline (or substituted aniline) is inhibited and (2) a lower limit of protic material which is the amount of protic material below which the desired selectivity for 4-ADPA intermediates is not maintained

ID at 78-79.

A. Claims at Issue

Claim 30 of the '063 patent reads as follows:

> 30. A method of producing 4-aminodiphenylamine (4-ADPA) comprising the steps of:
>
> a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and ***controlled amount of protic material*** to produce one or more 4-ADPA intermediates; and c) reducing the 4-ADPA intermediates under conditions which produce 4-ADPA.

CX1, Col. 14, ll. 16-26 (emphasis added). Claim 61 reads as follows:

> 61. A method of producing alkylated p-phenylenediamines comprising the steps of:
>
> a) bringing aniline and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline and nitrobenzene in

> a confined zone at a suitable temperature, and in the presence of a suitable base and ***controlled amount of protic material*** to produce one or more 4-ADPA intermediates. c) reducing the 4-ADPA intermediates to produce 4-ADPA; and d) reductively alkylating the 4-ADPA of Step c).

CX1, Col. 15, ll. 34-46 (emphasis added).

Claim 7 of the '111 patent reads as follows:

> 7. A method of producing 4-aminodiphenylamine (4-ADPA) or substituted derivatives thereof comprising:
>
> > a) bringing aniline or substituted aniline derivatives and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline or substituted aniline derivatives and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and ***controlled amount of protic material*** to produce one or more 4-ADPA intermediates; and c) reducing the 4-ADPA intermediates under conditions which produce 4-ADPA or substituted derivatives thereof wherein the amount of protic material in step (b) is controlled by the continuous distillation of said protic material.

CX3, Col. 20, l. 63 through Col. 21, l. 10 (emphasis added). Claim 11 reads as follows:

> 11. A method of producing alkylated p-phenylenediamines or substituted derivatives thereof comprising:
>
> > a) bringing aniline or substituted aniline derivatives and nitrobenzene into reactive contact in a suitable solvent system; b) reacting the aniline or substituted aniline derivatives and nitrobenzene in a confined zone at a suitable temperature, and in the presence of a suitable base and ***controlled amount of protic material*** to produce one or more 4-ADPA intermediates; c) reducing the 4-ADPA intermediates to produce 4-ADPA or substituted derivatives thereof; and d) reductively alkylating the 4-ADPA or substituted derivatives thereof of step (c) wherein the amount of protic material in step (b) is controlled by the continuous distillation of said protic material.

CX3, Col. 21, ll. 38-53 (emphasis added).

B. The Specifications

Generally, the '063 and the '111 patents describe a method for producing 4-ADPA intermediates and 4-ADPA itself by reacting or coupling aniline and nitrobenzene with a "suitable solvent" and a "suitable base" under conditions where the amount of protic material (*e.g.*, water) is controlled. Fu, Tr. 1292. Specifically, the specifications state that "the field of the invention" relates to "methods for preparing 4-ADPA wherein aniline is reacted with nitrobenzene in the presence of a base, and under conditions wherein *the amount of protic material*, *e.g.*, water, *is controlled*, to produce a mixture rich in the salt of 4-nitrodiphenylamine and/or the salt of 4-nitrosodiphenylamine." CX1, Col. 1, lns. 8-15; CX3, Col. 1, lns. 15-21 (emphasis added). Similarly, the "summary of the invention" sections of both patents describe the inventions as being directed to "a method of preparing 4-ADPA intermediates, and the salts thereof, and/or 4-nitrosodiphenylamine (p-NDPA) and/or the salts thereof, wherein aniline and nitrobenzene are brought into reactive contact in a suitable solvent system, and then reacted in the presence of a base and under conditions wherein *the amount of protic material*, such as water, *is controlled*." CX1, Col. 2, lns. 16-24; CX3, Col. 2, lns. 23-32 (emphasis added).

Each specification discloses that suitable solvent systems include six specified solvents: dimethylsulfoxide ("DMSO"), N-methylpyrolidone, dimethylformamide, aniline, pyridine, and nitrobenzene, as well as mixtures thereof. And, as noted, the specifications teach that the solvent mixtures used include a controlled amount of a protic material. Fu, Tr. 1297, 1305; CX1, Col. 3, lns. 37-47; CX3, Col.4, lns. 23-36. The specifications also disclose suitable bases that could be used in the reactions. Fu, Tr. 1297; CX1, Col. 3, lns. 48-64; CX3, Col.4, lns. 37-61. Moreover,

the specifications teach that the maximum amount of protic material is dependent upon the solvent/base combination selected. The specifications expressly disclose the specific maximum amount of protic material for only two of the six solvents when water is the protic material.

In this regard, the specification of each patent expressly states:

> Control of the amount of protic material present in the reaction is important. Generally, when the reaction is conducted in aniline, water present in the reaction in an amount greater than about 4% H2O, (based on volume of the reaction mixture) inhibits the reaction of the aniline with the nitrobenzene to an extent where the reaction is no longer significant. Reducing the amount of water to below the 4% level causes the reaction to proceed in an acceptable manner. When tetramethylammonium hydroxide is utilized as a base with aniline as the solvent, as the amount of water is reduced further, *e.g.*, down to about 0.5% based on the volume of the reaction mixture, the total amount of 4-nitrodiphenylamine and 4-nitrosodiphenylamine increases with some loss in selectivity so that more 2-nitrodiphenylamine is produced but still in minor amounts. Thus, the present reaction could be conducted under anhydrous conditions. A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H2O based on the volume of the reaction mixture when aniline is utilized as the solvent. The upper limit for the amount of protic material present in the reaction varies with the solvent. For example, when DMSO is utilized as the solvent and tetramethylammonium hydroxide ["TMAH"] is utilized as the base, the upper limit on the amount of protic material present in the reaction is about 8% H2O based on the volume of the reaction mixture. When aniline is utilized as a solvent with the same base [TMAH], the upper limit is 4% H2O based on the volume of the reaction mixture. In addition, the amount of protic material tolerated will vary with type of base, amount of base, and base cation, used in the various solvent systems. However, it is within the skill of one in the art, utilizing the teachings of the present invention, to determine the specific upper limit of the amount of protic material for a specific solvent, type and amount of base, base cation and the like. The minimum amount of protic material necessary to maintain selectivity of the desired products will also depend on the solvent, type and amount of base, base cation and the like, that is utilized and can also be determined by one skilled in the art.

CX1, Col. 4, ln. 31 through Col 5, ln. 4; CX3, Col. 5, lns. 27-65. As noted earlier, the above paragraph is generally referred to by the Judge throughout the ID as "the PARAGRAPH." *See* ID at 59-60.

The ID relies upon the general language in the last three sentences in "the PARAGRAPH" above as support for its conclusion that one of ordinary skill in the art would conclude that a controlled amount of protic material is an amount up to that which inhibits the reaction of aniline [or substituted aniline] with nitrobenzene and that a minimum amount of protic material is that necessary to maintain selectivity of the desired products' with no specificity to any particular solvent or reaction conditions. ID at 79, 82. The ID relied upon extrinsic evidence - - the testimony of Dr. Crich, Flexsys' expert - - in support of its determination that one of ordinary skill reading "the PARAGRAPH" as well as the patents in their entirety would conclude that there were no limits on any of the potential variables in a reaction, such as temperature, type or quantity of base, and reaction conditions. ID at 90-91.

As demonstrated below, the ID's construction of the limitation at issue is erroneous as a matter of law.

VI. ARGUMENT

A. The Id's Construction of the Limitation "Controlled Amount of Protic Material" Is Erroneous as a Matter of Law

1. In the Context of the Patents at Issue Here, the ID's Disregard of the Patentees' Express Definition Constitutes Reversible Error

As summarized above, the ID's construction of the "protic material" limitation failed to accord the appropriate weight to the patentees' express definition when arriving at its construction. The uncontroverted evidence of record is that the term "controlled amount of protic material" is not a term used in the chemical arts. *See*, *e.g.*, Bashkin, Tr. 407; Crich, Tr. 909-10; Fu, Tr. 1298, 1302-03, 1359. Indeed, Dr. Fu had never heard or seen the term prior to being retained in connection with this investigation. Fu, Tr. 1380.[12] Thus, the phrase appears to have been "coined" by the inventors of the patents at issue.

Where, as here, the term "controlled amount of protic material" has no precise or generally understood meaning in the art, one must look to the specification for guidance as to the meaning of that language as used in the patent. *See*, *e.g.*, *Phillips*, 415 F.3d at 1316 (in the instance where the inventor has dictated the correct claim scope - - by "special definition" or disavowal as expressed in the specification - - the inventor's intention, as expressed in the specification, *is regarded as dispositive*) (emphasis added); *Innova/Pure Water*, 381 F.3d at 1117

[12] The ID recognizes that the term "controlled amount of protic material" is not a term of art stating: "Such is especially pertinent in interpreting the claimed term 'controlled amount of protic material' because that term is not generally used in chemistry and has no clear meaning to readers. (RFF 4.10 (undisputed).) All parties have agreed that the meaning of 'controlled amount of protic material' depends at least 'on the context of the claim and the patent specification.' [cites omitted]." However, the ID ignores the express definition provided by the patentees.

("Because the inquiry into the meaning of claim terms is an objective one, a patentee who notifies the public that claim terms are to be limited beyond their ordinary meaning to one of skill in the art will be bound by that notification, *even where it may have been unintended*.") (emphasis added); *Abbott Labs*, 323 F.3d at 1330 (limiting scope of phrase "co-micronization of fenofibrate and a solid surfactant" to the definition set forth in specification because "the patentee has 'chosen to be his own lexicographer.'"); *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313,1324-25 (Fed. Cir. 2002) ("The words used in the claim are interpreted in light of the intrinsic evidence of record . . .. The intrinsic evidence may provide context and clarification about the meaning of claim terms. 'Such intrinsic evidence is the most significant source of the legally operative meaning of disputed claim language.'" (citations omitted)); *Durel*, 256 F3d at 1303-04 (Patentee's definition of the limitation in the specification controls); *Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1330-31 (Fed. Cir. 2000) ((Patentee's definition of the limitation in the specification controls); *Multiform Dessicants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998) (when the specification explains and defines a term used in the claims, without ambiguity or incompleteness*, there is no need to search further for the meaning of a term*) ("*Multiform Dessicants*") (emphasis added); *see also United States v. Adams*, 383 U.S. 39, 49 (1966) ("[C]laims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention."). Here there are quotation marks around the term "controlled amount" in the phrase a "*controlled amount of protic material*" in the specifications, and with respect to the base/solvent combination of aniline and TMAH, the specification

unequivocally states that the maximum amount of water is 4%. CX 1, Col. 4, ll. 48-60; CX 2, Col. 5, ll. 42-54.

The use of quotation marks around the term "controlled amount" clearly signals that the patentees are providing their definition of the term. Fu, Tr. 1301. The specification expressly sets forth a limitation for water by volume of "up to about 4%" when aniline is used as the solvent with any base other than tetramethylammonium hydroxide ("TMAH"), but when used with TMAH, the maximum amount of water by volume is 4%. *See*, *e.g.*, CX1, Col, 4, ll. 32-37, 48-52, 58-60; CX3, Col. 5, ll. 28-32, 43-46, 52-55. The specification also states that "about 8%" is the maximum amount of water by volume when DMSO is the solvent with TMAH as the base. CX1, Col. 4, ll.54-58; CX3, Col. 5, ll. 48-52.

Thus, OUII submits that the evidence clearly supports the proposition that the inventors acted as their own lexicographers when they expressly and unequivocally defined what constitutes a "controlled amount" when water is the "protic material" and aniline or DMSO is used as the solvent - - a maximum of "up to about 4%" H_2O by volume when aniline is the solvent with any base, except TMAH, "4%" with TMAH as the base, and a maximum of "about 8%" when DMSO is the solvent with TMAH as the base.[13] *See*, *e.g.*, *Phillips*, 415 F.3d at 1313;

[13] The ID states that OUII did not offer any proposed construction that would apply to solvents other than aniline and protic material other than water. ID at 79, n.23. The Judge is correct. OUII's analysis below emphasized aniline. However, OUII's discussion and analysis encompassed use of DMSO as the solvent. The specifications define the maximum limit of protic material when the protic material is water and the solvent is DMSO to 8% by volume. *See*, *e.g.* Commission Investigative Staff Post Hearing Brief at 13 ("up to 4% for aniline and "up to 8%" for DMSO). Finally, OUII believes that the dependent claims of the '063 patent make clear that, at a minimum, when the "suitable" solvent is aniline or DMSO and the protic material (continued...)

Astrazeneca, 384 F.3d at 1337; *Innova/Pure Water*, 381 F.3d at 1117; *Abbott Labs*, 323 F.3d at 1330; *Durel*, 256 F3d at 1303-04; *Cultor Corp.* , 224 F.3d at 1330-31; *Multiform Dessicants*, 133 F.3d at 1478.

"The PARAGRAPH" states, without qualification, that the amount of water is "up to about 4%" of the reaction when aniline is the solvent and that water is "about 8%" when DMSO is the solvent. However, the ID adopts Dr. Crich's testimony and concludes that these maximums show that they do not apply *under all reaction conditions* in view of other language in the PARAGRAPH. ID at 91, citing Crich, Tr. 1079-81, 1087-88, 1090-91. Thus, the ID erred as a matter of law by adopting a claim construction based on selected portions of the specification

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[13] (...continued)
is water, the percentage of protic material is independent of reaction conditions such as temperature, type or quantity of base or whether the reaction is aerobic or anaerobic.

The specifications do not provide any definition or example of what is, or would satisfy, the *minimum* parameter of the terms "rich," "desired selectivity," and/or the maximum parameter of the term "inhibit." Under these circumstances, OUII believes that any attempt to construe the term at issue in general terms to encompass all possible variations would inevitably result in a construction that is indefinite because each of the foregoing terms are subjective in the absence of a quantifiable target.

In any event, the specifications *define* the maximum allowable percentage of protic material *when* water is the protic material *and* either aniline or DMSO the solvent. Therefore, when either aniline or DMSO is the solvent *and* water is the protic material, one does not need to construe the term in the abstract for all conceivable combinations as the ID did here. *See*, *e.g.*, *Phillips*, 415 F.3d at 1316 (where the inventor has dictated the correct claim scope, the inventor's intention, as expressed in the specification, is regarded as dispositive); *Multiform Dessicants*, 133 F.3d at 1478 (when the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of a term).

and extrinsic expert testimony, while ignoring the express definition in the specification - - 4% for aniline and 8% for DMSO.[14]

Moreover, the ID relies upon terms such as "*e.g.*" in support of its determination that one of ordinary skill would not consider the limits set forth in "the PARAGRAPH" as absolute, relying again upon Dr. Crich's testimony. ID at 91. However, the availability of many solvents and protic materials identified in the specification, as well as an indeterminate number of unidentified "suitable solvents" and "protic materials," explains why the '063 and '111 patents use expressions such as "e.g." and "for example" before teaching express water limits for the two aniline and DMSO solvent systems. Irrespective of the foregoing, the ID ignores the specifications' express unqualified definition of the term "controlled amount of protic material" when aniline is the solvent and TMAH is the base (the precise combination used in the accused Sinorgchem process and in the Flexsys process), *i.e.*, "the upper limit *is* 4%." CX1, Col. 4, ll.58-60; CX 2, Col. 5, ll. 52-55 (emphasis added).

Under the Federal Circuit precedent cited immediately above, the ID's failure to accord the term the scope expressly defined in the specification constitutes error as a matter of law.

2. The ID's Reliance Upon Extrinsic Evidence that Contradicts Intrinsic Evidence Constitutes Reversible Error

As discussed above, the ID relies upon the testimony of Flexsys' expert as a basis for disregarding the express definition set forth in the specifications. The expert's testimony is also contrary to the teachings of other intrinsic evidence. For example, dependent claims 12, 13, 41,

[14] OUII notes that neither the ID nor Flexsys' submissions below address OUII's (or Respondents') contentions regarding whether the patentees acted as their own lexicographers.

42, 72, and 73 of the '063 patent demonstrate the fallacy of the ID's reliance upon extrinsic evidence in the form of Dr. Crich's testimony.

Claim 1 recites:

> 1. A method of producing one or more 4-ADPA intermediates comprising the steps of:
>
> a) bringing aniline and nitrobenzene into reactive contact *in a suitable solvent system*; and b) reacting the aniline and nitrobenzene in a confined zone *at a suitable temperature, and in the presence of a suitable base and controlled amount of protic material* to produce one or more 4-ADPA intermediates.

CX1, Col. 13, lns. 6-14 (emphasis added). Claim 12 recites a"[m]ethod of claim 1 wherein said solvent system *includes aniline and up to 4% water* based on the total volume of the reaction mixture." CX1, Col. 13, lns. 37-39 (emphasis added). Claim 13 recites a "[m]ethod of claim 1 wherein said solvent system includes dimethylsulfoxide and up to 8% water based on the total volume of the reaction mixture." CX1, Col. 13, lns. 40-43 (emphasis added). The language of dependent claims 41 and 42, which depend from asserted claim 30, is essentially identical to that in claims 12 and 13, respectively, differing only in that they recite "[m]ethod of claim 30" or "[m]ethod of claim 62, "which depends from claim 61 instead of "[m]ethod of claim 1."[15]

These claims, like the language in "the PARAGRAPH," specify, and indeed require, the identical "up to 4%" and "up to 8%" water for reactions when aniline and DMSO is used as the solvent and water is the protic material without *any* qualification as to reaction conditions, type or

[15] *See also* dependent claims 72 and 73, which depend from claim 62, and which limit the amount of water to "up to 4%" or "up to 8%" when aniline or DMSO, respectively, is used as the solvent.

quantity of base or whether the reaction is aerobic or anaerobic.[16] Thus, the intrinsic record demonstrates that Dr. Crich's opinion of how one would interpret the language of "the PARAGRAPH" is contrary to the intrinsic record.

3. The ID's Reliance upon a Later-filed application to Broaden the Scope of a Term Common to an Earlier Patent and Later-filed Applications Constitutes Error as a Matter of Law

The ID also erroneously relies upon actions and statements that occurred during the examination of the CIP application that issued as the '111 patent and the '111 patent, itself, as demonstrating that the maximum of protic material should not be limited to about 4% when

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[16] The ID contains a lengthy description of non-asserted independent and dependent claims. ID at 50-53. While the ID does not so state, its analysis in this regardt may have been based on the doctrine of claim differentiation. However, at least two reasons exist why claim differentiation does *not* apply in this investigation. First, where, as here, the patentee defines a claim term, claim differentiation arguments cannot alter a definition that is otherwise clear from the claim language, description, and prosecution history. *See O.I. Corp. v. Tekmar Co. Inc.*, 115 F.3d 1576, 1582 (Fed. Cir. 1997). In *O.I.*, the court stated: "We conclude that the description provides a clear meaning for the language of the claim in this case and that it trumps the doctrine of claim differentiation." *Id.*, 115 F.3d at 1582.

Second, claim differentiation does not apply here because claim differentiation *only* applies when the *sole* difference between the dependent claim and the independent claim is the limitation found in the dependent claim. *See*, *e.g.*, ID at 39-40; *see also*, *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314-15 (2005) (citing *Liebel-Flasheim*); *Liebel-Flarsheirn Co. v. Medrad, Inc.*, 358 F.3d 898, 910 (Fed. Cir. 2004).

Independent claims 1 and 30 recite a "suitable solvent system" and a "protic material." Claim differentiation might be applicable if the independent claims required aniline or DMSO as the solvent with any protic material or water as the "protic material" with any "suitable solvent" system. In either of those two circumstances, the limitations in these dependent claims, either the specific solvent or the specific protic material (and volume thereof) would be the sole difference between the independent and dependent claims. However, neither of the foregoing conditions are present here. Therefore, claim differentiation cannot apply to preclude limiting the water content of the independent claims to either 4% or 8% when aniline or DMSO, respectively, is used as the solvent.

aniline is used as the solvent. ID at 72-77, 87. The ID correctly cites *Omega Engineering Inc. v. Raytek Corp.*, 334 F.3d 1314, 1334 (Fed. Cir. 2003) for the proposition that the same terms in patents of common ancestry must be construed in the same manner. *See* ID at 79, n. 24. The ID, however, errs when it relies upon a later-filed application (the '111 patent) to broaden the scope of a common term found in both an earlier issued patent and the later-filed patent. In *Omega*, the patentee there, like Flexsys here, attempted to obtain a broader scope for a term present in both a patent that issued on the original application and in a later patent issued on a CIP application. The court, in *Omega*, held that the scope accorded the term in the first patent governed that of the same term in the latter, not *vice versa*. *Omega*, 334 F.3d at 1334. Thus, the ID legally erred in relying upon the prosecution of the '111 patent in support of its determination that the scope of the term "controlled amount of protic material" could be broadened by actions that occurred during prosecution of a CIP or the issuance of a patent based on the CIP that arguably supports a broader scope.

Moreover, the inventors did *not* change, or attempt to change, any of the language in "the PARAGRAPH" when they filed the CIP application. Thus, the language of "the PARAGRAPH" is identical in both parent and CIP. Under these circumstances, the ID's reliance upon the prosecution history of the CIP to the exclusion of the express definition found in the specifications of both patents constitutes legal error.

4. The ID's Requirement of a Showing that the Patentee Intended to Define the Term at Issue Constitutes Reversible Error

The ID also erred by requiring a determination that the patentees "intentionally define the term . . . ." (ID at 89) before applying their definition. The law is clear that an objective test is

used to determine whether a term is defined in the specification, rendering the intent of the patentee irrelevant. *See Innova/Pure Water*, 381 F.3d at 1117 ("Because the inquiry into the meaning of claim terms *is an objective one*, a patentee who notifies the public that claim terms are to be limited beyond their ordinary meaning to one of skill in the art will be bound by that notification, *even where it may have been unintended*.") (emphasis added). In view of the foregoing, the ID's focus on intent is error.

5. The ID's Requirement that Any Construction Encompasses All Examples Constitutes Error as a Matter of Law

The ID, relying upon the fact that every example in each of the patents is labeled a "preferred embodiment," and citing *Vitronics*, 90 F.3d at 1583 states: "construing a claim to exclude a preferred embodiment 'is rarely, if ever, correct and would require highly persuasive evidentiary support.'" "Persuasive evidentiary support" referred to in *Vitronics* includes the presence of an express definition such as is present here. *See Durel*, 256 F.3d at 1303-04. In *Durel*, the patentee argued that the definition of the term at issue in the specification is to be applied even though such application would exclude a preferred embodiment. In this regard, OUII notes that the court stated:

> Moreover, if the inventor had intended to equate metal oxides with metal hydroxides, *he could have so stated and avoided exclusively exemplifying metal oxides as binary compounds*. Therefore, according to the specification's explicit definition of "oxide coating" and its description of such coatings, the claimed oxide coating must primarily comprise binary metal oxides containing only metal cations and oxygen.

Durel, 256 F.3d at at 1303-04. Similarly, the patentees of the patents at issue did not have to limit the maximum amount of protic material in reactions were DMSO or aniline are used as

solvents and water is the protic material. However, having defined the term in such a fashion in both the parent and CIP, that definition should be applied, irrespective of whether it excludes "preferred embodiments."

The law is clear that claims do not have to encompass all examples disclosed in a patent specification. *See, e.g.*, *Telemac Cellular Corp. v. Topp Telecom., Inc.*, 247 F. 3d 1316, 1326 (Fed. Cir., 2001) (only certain of the disclosed embodiments satisfied claim term); *Novo Nordisk v. Genentech, Inc.*, 77 F.3d 1364, 1369 (Fed. Cir. 1996) ("While claims are to be interpreted in light of the specification, all that appears in the specification is not necessarily within the scope of the claims and thus entitled to protection") .

Finally, Flexsys' own inventors, Drs. Stern and Bashkin, indicated at trial that they did not consider all of their Example 3 experiments to necessarily be within the scope of the '063 and '111 patent claims. Stern, Tr. 614-19. Similarly, the '063 and '111 specifications teach that the Example 3 embodiment with 4.7% water did not proceed in an "acceptable manner" because it had a yield of only 0.05 millimoles. CX1, Col. 9, lns. 20-45; CX3, Col. 10, lns. 30-60. The testimony of Flexsys' inventors and the disclosures in the patents at issue illustrate why there is no requirement in the law that the claims cover "all the various embodiments" disclosed in the patent specification.

In sum, as demonstrated above, the specifications explicitly and unambiguously define the maximum volume of protic material in the reaction to be about 4% when water is the protic material and aniline is the solvent (and about 8% when water is the protic material and DMSO is the solvent). The law is clear that the patentee's definition is dispositive. *See*, *e.g.*, *Phillips*, 415

F.3d at 1316 (where the inventor has dictated the correct claim scope, the inventor's intention, as expressed in the specification, is regarded as dispositive); *Multiform Dessicants*,, 133 F.3d at 1478 (when the specification explains and defines a term used in the claims, without ambiguity or incompleteness, there is no need to search further for the meaning of a term). Therefore, for the purposes of this investigation where the reactions at issue use aniline as the solvent and water as the protic material, the term at issue should be construed as requiring a maximum of about 4% water.[17] In view of the foregoing, the ID's contrary construction is erroneous as a matter of law. Therefore, the Commission should grant review, and reverse the ID.

B. The ID's Determination That Sinorgchem Infringes Constitutes Reversible Error

The ID determined that Sinorgchem's process literally infringes the asserted claims based upon its construction of the limitation "controlled amount of protic material" which was the only disputed element. ID at 101-02.[18] In reaching this determination, the ID did not analyze

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[17] Therefore, as noted earlier, when either aniline or DMSO is the solvent and water is the protic material, one does not have to construe the term in the abstract for all conceivable combinations.

[18] In OUII's view, the ID's construction would lead to a finding of infringement of the asserted claims by almost any process wherein aniline and nitrobenzene are brought together in the presence of a base and measurable amounts of 4-ADPA intermediates are produced, which intermediates are then reduced and alkylated or merely reduced. For example, reduction of such intermediate to produce 4-ADPA would satisfy the elements of claim 30 of the '063 patent and claim 7 of the '111 patent. Similarly, alkylation of any such 4-ADPA to produce 6PPD would satisfy the elements of claim 61 of the '063 patent and claim 11 of the '111 patent.

The ID determined that the Wohl experiments do not satisfy elements a or b of claim 30 of the '063 patent or claim 7 of the '111 patent because Wohl allegedly does not teach the presence of a "solvent system" throughout the reaction or a "controlled amount of protic

(continued...)

Sinorgchem's process to determine how its alleged control of protic material relates to selectivity and inhibition. Rather, the ID merely concludes that Sinorgchem reacts the requisite reagents, controls the amount of water, and produces 4-ADPA intermediates, which are then reduced to 4-ADPA, which in turn is alkylated to produce 6PPD. ID at 98-102.

The uncontroverted evidence of record demonstrates that Sinorgchem's process would not be found to infringe the asserted claims if the proper construction of "controlled amount of protic material" - - maximum of 4% water when aniline is the solvent - - were to be applied because [

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[18] (...continued)
material" since Wohl evaporated all of the water from the reaction, and "did not maintain a minimum necessary to maintain the selectivity of the desired 4-ADPA intermediates." ID at 111-12.

The ID appears to have applied construction with respect to the Wohl reference that differs from that applied to infringement. For example, the ID states that the claims do not specify selectivity, temperature, base/solvent, or define "controlled amount" of protic material. ID at 49-50. The ID also recognizes that, during the prosecution of the '111 patent, the applicants asserted that Wohl disclosed the reaction of aniline with nitrobenzene in aniline as the solvent with NaOH as the base under anhydrous conditions." ID at 75. The specifications teach that the reaction could be anhydrous, *i.e.*, without water. CX1, col, lns 46-48; CX3, col. 5, lns. 41-43; ID at 59. However, the ID distinguishes Wohl based on its low selectivity, low yield, anhydrous nature, and the assertion that it was not a reaction of aniline with nitrobenzene. ID at 111-13.

In contrast, the European patent office ("EPO") and the Korean courts determined that the Wohl experiments satisfy these two elements and issued final rejections of the European and Korean counterparts of claim 1 of the '063 patent, which claim only requires the production of 4-ADPA intermediates, *i.e.*, the first two limitations of each of the asserted claims. *See*, *e.g.* EPC: Rains, Tr. 773; RX49 at 2; RX835 at 3, ¶2.2, at 5, ¶2.5, at 6, ¶2.6; RX43 at FA030508; RX848 at KKPC-ITC 09164T, KKPC-ITC 09168T, KKPC-ITC 09168T).

] [19] Therefore, under the proper claim construction, Sinorgchem's process cannot literally be found to literally infringe any of the asserted claims.

Moreover, Sinorgchem's process coannot be found to infringe under the doctrine of equivalents in light of the express definition. The specifications state that "the upper limit is 4% H2O"[

] Moreover, the inventors expressly disavowed coverage of methods wherein more than 4% water by volume is used when aniline is the solvent (irrespective of base and when aniline is the solvent and TMAH is the base). Under these circumstances, a finding of infringement under the doctrine of equivalents would require coverage of disclaimed matter. Therefore, this element cannot be satisfied under the doctrine of equivalents. *Astrazeneca*, 384 F.3d at 1342; Alloc, 342 F.3d at 1370; *SciMed*, 242 F.3d at 1345. As the court in *Astrazeneca* stated:

> The specification's clear disavowal of nonsurfactant solubilizers precludes the application of the doctrine of equivalents to recapture the disavowed solubilizers. *See*, *e.g.*, *Gaus v. Conair Corp.*, 363 F.3d 1284, 1291 (Fed. Cir.2004) ("Having disavowed coverage of [particular] devices ... the patentee cannot reclaim that surrendered claim coverage by invoking the doctrine of equivalents."); *SciMed*, 242 F.3d at 1345 ("A particular structure can be deemed outside the reach of the doctrine of equivalents because that structure is clearly excluded from the claims whether the exclusion is express or implied.").

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[19] Under the proper claim construction, Flexsys' process would not be found to practice any claim of the asserted patents on the same basis that Sinorgchem's process would be determined to be non-infringing. The water content at the beginning of Flexsys' process is approximately 20% by volume and it is approximately 8.5% at the end of the coupling reaction. ID at 121; Rains, Tr. 762-63, 764. Therefore, under the proper claim construction, Flexsys does not practice any claim of the asserted patents for the same reasons that it has not demonstrated that Sinorgchem's process infringes.

Astrazeneca, 384 F.3d at 1342. The inventors herein expressly disavowed coverage of methods that use water in excess of 4% twice: when aniline is the solvent ("up to about 4% water"), irrespective of type or quantity of base, temperature or reaction conditions, and again when aniline is the solvent and tetramethylammonium hydroxide is the base (maximum "is 4%"), irrespective of quantity base, temperature or reaction conditions. Therefore, Flexsys cannot recover claim coverage under the doctrine of equivalents.

As demonstrated above, the ID's determination that Sinorgchem's process infringes the asserted claims constitutes legal error, and, hence, that determination should be reversed.

C. The ID's Determination That the Asserted Claims Are Definite Constitutes Legal Error

The ID adopted Flexsys' proposed construction and determined that the term should be construed as follows:

> The term a "controlled amount" of protic material means that the amount of protic material (which is not limited to water) should be controlled between (1) an upper limit of protic material which is the amount of protic material beyond which the reaction between nitrobenzene and aniline (or substituted aniline) is inhibited and (2) a lower limit of protic material which is the amount of protic material below which the desired selectivity for 4-ADPA intermediates is not maintained

ID at 79. The ID determined that the above construction is definite, stating:

> In view of the specific preferred embodiments (examples) included in the specifications of the '063 and '111 patents, as well as the prosecution history of said patents *see supra*, the administrative law judge finds that such a person would not find the claimed term in issue indefinite. Thus he finds that the specifications provide a number of examples through controlled experiments that would permit said person to determine the specific upper and lower limits of protic material for a specific set of reaction conditions and that the prosecution history even provides calculations.

ID at 116. In reaching this conclusion, however, the ID does not identify a single example that would enable one to determine either the upper or lower limit of protic material required to satisfy any of the claims. It is noteworthy that none of the examples of either the '063 or the '111 patent expressly or implicitly teach either the upper or lower limits of protic material, or any objective criteria for determining such limits. *See* ID at 62-72. Similarly, the file history of the '111 patent, which the ID extensively relies upon, does not expressly or implicitly teach such limits. *See* ID at 72-77.

The examples and the prosecution history may teach one how to practice the "invention" (enablement under § 112, ¶ 1). However, enablement and definiteness serve different purposes and have distinct requirements. Therefore, the satisfaction of enablement does not necessarily satisfy the definiteness requirement, the claim must have a clear and definite meaning when construed by one of ordinary skill in the art in light of the specification. *Miles Laboratories, Inc. v. Shandon Inc.*, 997 F.2d 870, 874-75 (Fed. Cir.) *cert. denied*, 114 S.Ct. 943 (1994). As the court stated in *Miles*, "Shandon's argument is irrelevant to definiteness under § 112, ¶ 2. The invention's operability may say nothing about a skilled artisan's understanding of the bounds of the claim. Shandon's argument is possibly relevant, however, to the enablement requirement of § 112, ¶ 1, or to utility under § 101." *Miles*, 997 F.2d at 875.

After mentioning Respondents' argument relating to the *Exxon* decision, the ID concludes: "In this investigation, the administrative law judge finds that the specifications of the '063 and '111 patents provide a number of examples through controlled experiments that permit one skilled in the art to determine the specific upper and lower limits of protic material for a specific set of

reaction conditions. ID at 117. As previously discussed, however, the ID does not identify any specific examples that would permit one of ordinary skill in the art to determine either the upper or lower limit, or explain how one would do so. Further, a review of the evidence proffered at the evidentiary hearing by Flexsys demonstrates that the determination is purely subjective. For example, none of Flexsys' witnesses were able to identify *any* objective parameter that could be used to determine what constitutes the upper or the lower limit of the phrase "controlled amount of protic material," or the amount of inhibition or the degree of selectivity encompassed within the claim limitation.

For example, Dr. Crich, Flexsys' technical expert on infringement, testified that water content in an amount that results in a yield of 20% would not be considered to be an amount that inhibited the reaction. Crich, Tr. 1076.[20] He further testified as to what would constitute a "good yield," by stating: "It all depends what you're seeking to do." Crich, Tr. 1008. According to an inventor, Dr. Bashkin, the claims at issue are infringed when the yield of an accused process is "[r]ich enough to satisfy that potential infringer that 4-ADPA can be made successfully and in a commercially viable manner from the mixture of those." Bashkin, Tr. 394. Dr. Bashkin further explained that "richness depends, *inter alia*, on what country you are in and what the raw materials costs and energy costs are" and that "it is an economic and business decision, as much as a chemistry decision, or even more so. And that's why it is left to – it has to be left to the

[20] Under this scenario, water would have inhibited the conversion of nitrobenzene by approximately 80%.

individual practitioner, if they feel the chemistry is effective enough to practice, and practice it, then they have made the decision that it is rich enough for their purposes." Bashkin, Tr. 400-01.

Dr. Stern, the other named inventor, offered similar testimony. According to Dr. Stern, the term "richness" understood to be "a function of what the user considers to be optimized for his or her purposes." Stern, Tr. 630. Therefore, under Dr. Stern's construction, the determination of what constitutes "rich" is based on the subjective determination of the researcher.

Moreover, even using the data in Example 8 of the '063 and '111 patents, where the type and amount of base, the type and amount of solvent, the temperature, and the pressure have all been specified, Dr. Bashkin, one of the two named inventors, ***could not*** determine, or describe how one would be able to use that data to determine the minimum or maximum amounts of protic material that should be used to obtain acceptable yields and selectivity. Bashkin, Tr. 2148:19-2150:25; CX1, Col. 11, ll. 9-33; CX3, Col. 12, ll. 25-50. To the same effect, *see* Bashkin, Tr. 444; Stern, Tr. 651; Rains, Tr. 790-92, 794; Crich, Tr. 1007–09.

Moreover, as shown below, the ID's reliance upon *Exxon Research & Eng.'g v. United States*, 265 F.3d 1371 (Fed. Cir. 2001) (ID at 117-18) is misplaced because *Exxon* supports the contrary determination, *i.e.*, the limitation is indefinite.

Three terms were in issue in in *Exxon*: (1) "to increase substantially;" (2) "for a period sufficient to;" and (3) "substantial absence of slag flow." *Exxon*, 265 F.3d at 1377, 1378, 1381. The *Exxon* court found that each of the terms were definite based on the following:

(1) "to increase substantially"

The patent in *Exxon* provided a "target" and the specification disclosed two different methods of calculating the desired target. However, each method would lead to significantly different results. The Court stated that the term was definite because: "We disagree with the court's conclusion as to the indefiniteness of the phrase 'to increase substantially.' The specification makes it reasonably clear that *the patentee intended to use the subtraction method in calculating relative productivity." Exxon*, 265 F.3d at 1377 (emphasis added). Thus, in *Exxon*, while the specification described two different methods of calculation that could be used to determine the limitation, it identified the specific method that should be used. In contrast, with the exception of the "about 4%," "4%," and "about 8%" targets rejected by the ID, neither the claims at issue nor the specifications provide an objective target. Therefore, the question of whether one of ordinary skill in the art would be able to calculate such volume is irrelevant.

(2) "for a period sufficient to [productivity]"

Despite the fact that the specification did not disclose a higher or lower limit for the requisite period, the Federal Circuit in *Exxon* held that the term was definite, stating:

> Although the patent does not quantify the "period sufficient" limitation by reference to any specific period or range of periods, it does not leave those skilled in the art entirely without guidance as to the scope of that requirement. The specification states:
>
> > The period necessary for activation is that period that results in substantial increases in initial, *e.g.*, start of run, catalyst productivity, *preferably at least about a thirty percent (30%) increase in relative catalyst productivity and may vary with temperature and treat ratio, etc., but is usually accomplished in about 0.25-24 hours, preferably about 0.5-2 hours*.

> '705 patent, col. 2, ll. 58-64. As the trial court noted, the specification does not give a specific example of a period of time sufficient to achieve a particular increase in catalyst productivity for a certain supported catalyst. *However, a preferred treatment period is provided that presumptively correlates to the preferred catalyst, hydrogen treat rate range, and temperature range disclosed in the specification.* ***By looking to the specification, one of skill in the art could determine that "a period sufficient" is about 0.25 hours, and preferably 0.5 hours.*** Because the patent makes clear that the period in question will vary with changes in the catalyst and the conditions in which the process is run, we conclude that the claim limitation is expressed in terms that are reasonably precise in light of the subject matter.

265 F.3d at 1379 (emphasis added). The court rejected the defendant's reliance on *In re Jolly*, 172 F.2d 566 (CCPA 1949), wherein a similar limitation had been rejected, on the basis that the specification in *Jolly* did not disclose a lower limit *and* the specification taught that the *reaction time was critical*. The *Exxon* court distinguished *Jolly* on two grounds: (1) unlike *Jolly*, the specifications in *Exxon* set forth a lower limit (265 F.3d at 1380), and (2) unlike *Jolly* where the specification taught that the limitation was critical, the specifications of the patents in *Exxon* did not contain any such representation. The court stated:

> Moreover, *the specification in Jolly taught that reaction time was critical to the patentability of the invention*, and the court emphasized that point in holding the claim language indefinite. *There is no equivalent representation as to the criticality of the treatment period in this case*, and in a post-Jolly decision, the Court of Customs and Patent Appeals explained that it is not fatal for an applicant *to express noncritical limitations with regard to factors such as time or quantity in functional rather than numerical terms*.

Exxon, 265 F.3d at 1380 (emphasis added). Unlike *Exxon*, in the present case the specifications and file history of the patents *emphasize* the criticality of the "controlled amount of protic material" limitation to the inventions. *See*, *e.g.*, ID at 54-61, 75-77. Moreover, unlike *Exxon*, the specifications at issue here do not disclose *either* a *lower or upper* limit. Thus, the ID's

conclusion that the limitation at issue is definite, based on the specifications' disclosure of "a number of examples through controlled experiments . . . and that the prosecution history even provides calculations" (ID at 116), is *not* supported by *Exxon.* Since the "controlled amount of protic material" limitation is critical, application of the *Exxon* court's rationale requires the presence of objective upper and lower limits in the specifications. Since the specifications do not provide either limit under the ID's claim construction, *Exxon* does not support the ID's determination that the limitation at issue satisfies the definiteness requirements of § 112, ¶ 1.

(3) "substantial absence of slag flow"

The Federal Circuit determined that this limitation was definite stating:

> Whether there is a "substantial absence of slug flow" therefore can be determined with reference to whether reactor efficiency is materially affected. If there is no slug flow or such minimal slug flow that the slug flow has no appreciable impact on reactor efficiency, then there is a "substantial absence of slug flow" within the meaning of the claims. In this setting, as in others, mathematical precision is not required--only a reasonable degree of particularity and definiteness.

Exxon, 265 F.3d at 1381. The ID also relied upon this statement in support of its conclusion, stating:

> Similar to the patent in issue in Exxon, the patents in issue in this investigation teach that too much protic material can inhibit the reaction of aniline and nitrobenzene (CX-1, col. 4., Ins. 48-50); that the upper limit can be determined by those skilled in the art "utilizing the teachings of the present invention"' which includes all of the specific preferred embodiments (the examples) &I.,col. 4, Ins. 64-65);and, that the upper limit will vary "for a specific solvent, type and amount of base, base cation and the like." (*Id.* col. 4, Ins. 66-68.) The same is true of the lower limit of protic material, which affects selectivity of the desired products. &I.,col. 4, In. 68-col. 5, In. 4.) Thus, the administrative law judge finds that the specifications provide, through the general teaching of the patents in issue (CX-1, col. 4, In. 61 - col. 5, In. 4, CX-3, col. 5, Ins. 27-65) and through several controlled experiments, a number of benchmarks that inform one skilled in the art the effect of controlling protic material on conversion and selectivity.

ID at 117. As demonstrated above, the ID's conclusion above is *not* supported by *Exxon* because *Exxon*, when distinguishing *Jolly*, made clear that specific targets have to be provided when dealing with *critical* limitations.

In sum, the limitations at issue in *Exxon* were determined to be definite because the specification provided *specific* targets to be met, or the specifications did not represent that the limitation was *critical* to the invention. In contrast, the specifications at issue do not provide *any* specified target, *and* the specifications emphasize the *criticality* of the upper and lower limits of the "controlled amount of protic material" limitation. In view of the foregoing, *Exxon* does not support the ID's definiteness determination.

In OUII's view, the facts in *Datamize LLC v. Plumtree Software Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005) are on all fours with the instant case. The ID concludes that *Datamize* is distinguishable, stating:

> In this investigation, the administrative law judge finds that the disclosures of the '063 and '111 patents, supplemented by the prosecution history, do provide an objective definition for the claimed term "controlled amount of protic material" to a person having a masters degree in organic chemistry and some experience in the art of making 4-ADPA and having awareness of all pertinent prior art. In other words, he finds a person "experienced in the field" of the invention in issue, and not merely a person with no chemical background, would understood the meaning of "controlled amount of protic material" in view of the claims and the specifications of the '063 and '111 patents and the prosecution history.

ID at 118-19. The ID, however, does not explain the differences between the absence of objective standards in *Datamize* for the phrase "aesthetically pleasing" and the similar absence of objective standards in the patents at issue for the term "a controlled amount of protic material."

In *Datamize*, the patentee argued that the term "aesthetically pleasing," when used in the context of the claims, applied to the process of defining a "'desired result' and not the actual process itself." *Datamize*, 417 F.3d at 1349. The Federal Circuit held that the desirability of the "aesthetically pleasing" result does not change the inherent subjectivity of the term. *Id.*, 417 F.3d at 1349-1350. Similarly, the ID contends that the term "controlled amount of protic material" applies to the process of defining "desired selectivity" and "inhibition." ID at 80 (upper and lower limits), at 115-16. Here, as in *Datamize*, however, the fact that a level of selectivity or inhibition is desired does not alter the inherent subjectivity of the term.

In *Datamize*, the Federal Circuit rejected patentees' reliance upon general statements in the specification, stating:

> In general, neither of these statements nor any others in the written description set forth an objective way to determine whether an interface screen is "aesthetically pleasing." The description of the advantages of the invention indicates that there are "good standards of aesthetic," which of course implies that there are also standards of aesthetics that are "not good." The inventor does not attempt to explain what distinguishes the two, except to say that experts, specialists, and academics may have view that are influential in determining what aesthetic standards are good.

Datamize, 417 F.3d at 1352. Similarly, the ID states that the "Background of the Invention" and the "Summary of the Invention" sections of the '063 and '111 patents teach that the amount of protic material (*e.g.*, water) is controlled to produce a mixture that is "rich in 4 ADPA intermediates." ID at 54-56. This, of course, implies that there are also amounts of protic material that produce mixtures that are not "rich." The specifications of the '061 and '111 patents do not distinguish "rich" from not "rich." The ID also contends that the patents teach those of ordinary skill how to achieve the lower limit "below which the *desired* selectivity is not

maintained." ID at 79 (emphasis added). The ID simply concludes that "a person 'experienced in the field' of the invention in issue, and not merely a person with no chemical background, would understood [*sic*] the meaning of 'controlled amount of protic material' in view of the claims and the specifications of the '063 and '111 patents and the prosecution history." ID at 119. Here as in *Datamize*, these statements do not set forth an objective way to determine whether an amount of protic material produces a mixture that is "rich" or not "rich."

In *Datamize*, the patentees argued that the description provides examples of aesthetic features of screen displays. However, the Federal Circuit stated that the examples fail to "explain what selection of these features would be 'aesthetically pleasing.'" *Datamize*, 417 F.3d at 1352. Similarly, Flexsys contended below that the examples in the '063 and '111 patents provide "experimental benchmarks," as well as an explanation of how various reaction variables and others "can affect the upper and lower limits of the amount of protic material tolerated under specific reaction conditions." ID at 115. However, here as in *Datamize*, the examples in the '063 and '111 patents provide no explanation nor do they identify which, if any, amount of protic material would result in a "desired" amount of selectivity or acceptable level of yield, as encompassed by the claimed term.

Also, here, as in *Datamize*, the patentees presented experts attempting to "identify parameters that one skilled in the art might reference when attempting to determine whether an interface screen is 'aesthetically pleasing." *Datamize*, 417 F.3d at 1354. The Federal Circuit rejected the experts' declarations, noting that "[t]he inability of the expert to use the parameters he himself identified to determine whether an interface screen is 'aesthetically pleasing' militates

against the reasonableness of those parameters as delineating the metes and bound of the claim." *Datamize*, 417 F.3d at 1354. Similarly, as discussed above, Flexsys presented three named inventors, Drs. Stern, Bashkin and Rains, as well as its chemistry expert, Dr. Crich, all of whom attempted to identify parameters that affect the degree of desired richness and yield. Therefore, as in *Datamize*, the inability of the inventors and experts to determine the parameters of reaction conditions that would be encompassed by the claims demonstrates the subjectivity of the metes and bound of the claim.

In view of the foregoing, the ID's "finding" that "the disclosures of the patents at issue, supplemented by the prosecution history, do provide objective support for the 'claimed term . . . ." (ID at 119) is *not* supported by the evidentiary record. As such, OUII submits that the ID's conclusion that the term as construed satisfies the definiteness requirements of § 112, ¶ 2 is reversible error.

VII. CONCLUSION

As demonstrated above, the ID's construction of the term "controlled amount of protic material" is erroneous as a matter of law, thereby resulting in erroneous legal determinations that Sinorgchem's process infringes the asserted claims and that Flexsys' process practices such

claims. Moreover, the ID's determination that such construction is definite, and thus valid under Section 112, ¶ 2 is legally erroneous and thus review and reversal on this issue is also warranted.

Respectfully submitted,

S/ Juan Cockburn

Lynn I. Levine, Director
Jeffrey R. Whieldon, Supervisory Attorney
Juan Cockburn, Investigative Attorney

OFFICE OF UNFAIR IMPORT INVESTIGATIONS
U.S. International Trade Commission
500 E Street, S.W., Suite 401-Q
Washington, D.C. 20436
(202) 205-2572
202/205-2158 (Facsimile)
juan.cockburn@usitc.gov

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Certain Rubber Antidegradants , Components Thereof, and Products Containing Same Inv. No. 337-TA-533

PUBLIC CERTIFICATE OF SERVICE

I, Juan Cockburn, hereby certify that on March 14, 2006 copies of the foregoing **PETITION OF THE OFFICE OF UNFAIR IMPORT INVESTIGATIONS FOR REVIEW OF FINAL INITIAL DETERMINATION AND RECOMMENDED DETERMINATION (*PUBLIC VERSION*)** were served by hand upon Administrative Law Judge Paul J. Luckern (three copies) and upon the following parties by electronic mail.

For Complainant Flexsys America L.P.

Gregory C. Dorris, Esq. (202) 220-1224
Charles H. Carpenter, Esq.
PEPPER HAMILTON LLP
Hamilton Square
600 Fourteenth Street, NW
Washington, DC 0005-20040
(202) 220-1200 (Telephone)
(202) 220-1665 (Facsimile)
dorrisg@pepperlaw.com

Eric C. Cohen, Esq. (312) 902-5648
Charles R. Krikorian, Esq.
Carolyn E. Miller, Esq.
KATTEN MUCHIN ROSENMAN LLP
525 West Monroe Street
Chicago, Ill. 60661-3693
(312) 902-5200 (Telephone)
(312) 902-1061 (Facsimile)
eric.cohen@kmzr.com

For Respondent Korea Kumho Petrochemical Co. Ltd

Byron W. Cooper, Esq.
Mark T. Jansen, Esq.
Joel G. Ackerman,, Esq.
TOWNSEND AND TOWNSEND AND CREW
Two Embarcadero Center
Eight Floor
San Francisco, CA 94111
(415) 576-0200 (Telephone)
(415) 576-0300 (Facsimile)

Robert G. Badal, Esq. (213) 689-7645
Edward J. Slizewski, Esq. (213) 689-
HELLER EHRMAN LLP
333 S. Hope Street, Suite 3900
Los Angeles, CA 90071-3043
(213) 689-0200
(213) 614-1868

V. James Adduci, Esq.
Barbara A. Murphy, Esq.
Maureen L. Browne, Esq.
ADDUCI, MASTRIANI & SCHAUMBERG
1200 Seventeenth Street, N.W.
Washington, DC 20036
(202) 467-6300 (Telephone)
(202) 466-2006 (Facsimile)

Alan H. Blankenheimer, Esq. (858) 450-5817
HELLER EHRMAN LLP
4350 La Jolla Village Drive 7th Floor
San Diego, CA 92122
(858) 450-8400(Telephone)
(858) 450-8499 (Facsimile)

For Respondent Sovereign Chemical Company

James K. Kearney, Esq.
WOMBLE, CARLYLE, SANDDRIDGE & RICE LLP
1401 I Street, NW, 7th Floor
Washington, D.C. 20005
(202) 857-4514 (Telephone)
(703) 918-2269 (Facsimile)

Nanda K. Alapi, Esq. (703) 394-2216
WOMBLE, CARLYLE, SANDDRIDGE & RICE LLP
8065 Leesburg Pike, 4th Floor
Tysons Corner, Virginia
(703) 394-2216 (Telephone)
(703) 790-2623 (Facsimile)

Deborah A. Coleman, Esq.
HAHN, LOESER & PARKS LLP.
501 S. Main Street
200 Public Square
3300 BP Tower
Cleveland, Ohio 44114
(216) 274-2220 (Telephone)
(216) 241-2824 (Facsimile)

Scott M. Oldham, Esq.
John J. Cunniff, Esq.
HAHN, LOESER & PARKS LLP
One GOJO Plaza, Suite 300
Akron, Ohio 44311-1076
(330) 864-5550 (Telephone)
(330) 864-7986 (Facsimile)

For Respondent Sinorgchem Co.

Paul J. Zegger, Esq.
Zhiqiang Zhao, Esq.
ARNOLD & PORTER
555 Twelfth Street,N.W.
Washington, D.C. 20004-12206
(202) 942-5000 (Telephone)
202) 942-5999 (Telephone)

Marcia H. Sundeen, Esq.
1700 Pennsylvania Avenue, N.W., Suite 400
Washington, D.C. 20006
202-349-3673 (Telephone)
202-349-3674 (Facsimile)
Marcia@sundeenlaw.com

S/ Juan Cockburn

Juan Cockburn
Commission Investigative Attorney
OFFICE OF UNFAIR IMPORT INVESTIGATIONS
U.S. International Trade Commission
500 E Street, S.W., Suite 401
Washington, D.C. 20436
(202) 205-2572, FAX (202) 205-2158
juan.cockburn@usitc.gov